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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,571	07/23/2003	Alexander B. Maurer	240636US0X	6620

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EXAMINER

VALENROD, YEVGENY

ART UNIT PAPER NUMBER

1621

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/624,571	Applicant(s) MAURER ET AL.	
	Examiner Yevgeny Valenrod	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 19,20 and 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/23/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/16/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-4 and 21, in the reply filed on May 8th 2006 is acknowledged. The traversal is on the grounds that the search would not constitute a serious burden on the Office. This is not found persuasive because search of the generic compound of claim 1 alone constitutes searching different classes/ subclasses. The searching the various methods of preparation/treatment presents further burden on the office.

The requirement is still deemed proper and is therefore made FINAL.

Since applicant elected Group I, which is directed to a compound of formula (I), if the claims included in group I are found allowable, the withdrawn process claims which depend from or include all the limitations of the allowable process claims will be rejoined.

Claims 19, 20 and 22-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups II and III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 8th 2006.

Drawings

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The drawings are objected to because drawings 2 and 5 are incomprehensible and lack sufficient description in the specification. While drawing 2 is explained on page 20, the drawing does not support the specification because the drawing is incomprehensible. Also, in the specification the applicant states that the minimum concentration where compounds 1 and 2 show activity is $1,6\mu\text{M}$, however the scale of Figure 2 does not show a concentration lower than $1,6\mu\text{M}$ for compound 1 so it is not clear how one is to compare even if the drawing in Figure 2 was comprehensible. Drawing in the Figure 5 is incomprehensible and lacks description in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “physiologically functional derivative” is indefinite. Examiner acknowledges that the said term is defined in the specification on page 7. However, despite the specific prodrugs recited in the specification the term is not limited to those compounds. Claim 4 therefore includes physiologically functional derivatives that were not covered in the specification and are not clear to those of ordinary skill in the art.

2. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites the limitation “human histone deacetylase”. There is insufficient antecedent basis for this limitation in the claim. Claim 21 depends on claim 4 and there is no mention of “human histone deacetylase” in claim 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobsen (US 5,712,300). Column 38 Example 20, Jacobsen discloses a method of preparing N³-Hydroxy-N¹-methyl-3-(2-methylpropyl)-2-oxo-1,3-pyrrolidinediacetamide, which anticipates the compound of formula (1) of the instant claim 1. The disclosed compound contains: a hydroxyamide functionality, a non-aromatic ring system of two to seven carbons, X = CH₂, p = 0, Z = C (X, p and Z are as defined in claim 1 of the instant application). According to claim 1 arbitrary substitution on the ring is allowed.

5. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Beckett et al. (WO 98/52910).

Beckett et al. disclose a compound of the instant claims 1-4. The said compound is the last product of scheme 1 on page 24. It anticipates the compounds of the instant claims 1-4 when: n = cyclopentyl, Z = CH, X = CH and p = 0 (n, Z, X and p are as depicted in the compound of formula (I) of the instant claim 1). According to claim 1 arbitrary substitution on the ring is allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frederick et al. (EP 0 200 377 B1).

Claims 1-4 of the instant application are directed to the compound of formula (I). Claims 2 and 3 further limit the scope of the generic claim by defining the ring type as cyclopentyl or cyclohexyl and identifying Z as CH.

Scope of prior art

Haslanger et al. teach N-Cyclohexyl-N-hydroxycyclohexaneacetamide (page 18, Example 19) and a method for treatment of allergies, comprising the said compound or other structurally related compounds (page 2, lines 1-13). The said compound has a cyclohexane ring and the variable Z (as defined in the instant claim 1) = CH.

Ascertaining the difference between prior art and the instant claims

In the compound taught by Haslanger et al., N-Cyclohexyl-N-hydroxycyclohexaneacetamide, the Nitrogen is substituted with a cyclohexyl substituent. The instant claims 1-4 limit the substitution at that position to a Hydrogen atom.

Obviousness

N-Cyclohexyl-N-hydroxycyclohexaneacetamide has utility as an anti-allergy agent (page 2 lines 1-13). The only difference between the instantly claimed compounds and N-Cyclohexyl-N-hydroxycyclohexaneacetamide is the N-cyclohexyl substituent in place of the N-Hydrogen in the instant claims. However, Haslanger et al. teach that the N-cyclohexyl substituent can be replaced with hydrogen (page 2, lines 5-13) and the resulting structure still will retain its anti allergenic properties, which renders

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the compounds of the instant application obvious over Haslanger et al.'s example 19 (page 18). One of ordinary skill in the art would therefore be motivated to make N-hydroxycyclohexaneacetamide, which is the N-Hydrogen substituted derivative of N-Cyclohexyl-N-hydroxycyclohexaneacetamide. There is reasonable expectation that the derivative would work as anti-allergy agent since Haslanger et al. have already suggested it (page2, line 13).

Conclusion

Claims 1-4, 19-31 are pending in the application.

Claims 19, 20, 22-31 are withdrawn as being drawn to non-elected subject matter.

Claims 1-4 and 21 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

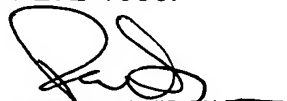
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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